REMARKS

Claims 1, 4, 42, 43, and 45-56 are pending. Claims 1, 4, 42, 43, and 45-56 are rejected under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 102. Applicants address each of these bases for rejection as follows.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 1, 4, 42, 43, and 45-56 stand rejected under 35 U.S.C. § 112, first paragraph for an asserted lack of written description in the specification as filed. The Office states (page 3):

> It remains unclear what the structure is of the tumor-specific N-linked glycostructure. Location of the single N-linked glycosylation site on CD55 is not the same as knowing the structure. In view of Applicants not being able to define, nor characterize the glycostructure, one of ordinary skill in the art is not clear on the variability that possibly exists within the genus of glycoproteins.

Applicants respectfully disagree.

The claimed invention

Claim 1 is directed to an isolated glycoprotein containing the human amino acid primary structure of CD55 and a tumor-specific N-linked glycostructure. The claim further requires the glycoprotein to have an apparent molecular weight of about 82 kD in sodium dodecyl sulfate ("SDS") polyacrylamide gel electrophoresis and to be a glycoprotein present on adenocarcinoma cell line 23132, but not on a normal cell. The

glycoprotein of claim 50 is required to contain a section of a glycosylated human CD55 protein expressed by adenocarcinoma cell line 23132, but not by a normal cell. The glycosylated human CD55 protein has an apparent molecular weight of about 82 kD in SDS polyacrylamide gel electrophoresis, and the section of the glycosylated human CD55 protein includes a tumor-specific N-linked glycostructure.

The N-linked glycostructure

Contrary to the Office's contention, the specification as filed meets the written description requirement of 35 U.S.C. § 112, first paragraph, for the tumor-specific N-linked glycostructure recited in the present claims. The tumor-specific N-linked glycostructure is present on the 82 kD (in SDS polyacrylamide electrophoresis) glycoprotein containing the amino acid primary structure of CD55 which is present on the 23132 cell line, but not a normal cell.

The specification describes the 23132 cell line as being deposited in a public depository (the DSMZ) under accession number DSM ACC 201. For example, at page 5, lines 12-18, of the English language text, the specification states:

> In SDS-polyacrylamide-gel electrophoresis ... such a glycoprotein that can be obtained from, for example, human adenocarcinoma cell line 23132 (DSM ACC 201) ... has an apparent molecular weight of about 82 kD.

Applicants, in the December 5, 2005 and October 11, 2006 replies noted that, in *Enzo Biochem*, the Federal Circuit has held that one may comply with the written description

requirement by publicly depositing the biological material. The Court stated:

> [R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, *constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1.* (emphasis added)

Enzo Biochem, Inc., v. Gen-Probe Inc., 296 F.3d 1316, 1325 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002).

In *Enzo Biochem*, the deposits were recombinant bacterial cells expressing the DNA molecules of interest; the deposited cells provided adequate written description for the DNA molecules even though the sequence of the DNA molecules was not set forth in the specification. Given that Applicants' specification describes a publicly deposited cell line expressing a glycoprotein having the glycostructure encompassed by the present claims, Applicants submit that the description of the glycostructure in Applicants' specification meets the written description standard set forth by the Federal Circuit in *Enzo Biochem*. In view of the deposit, *Enzo Biochem* supports Applicants' position that the glycostructure need not be characterized by chemical structure to meet the written description requirement of 35 U.S.C. § 112, first paragraph. The Office fails to provide any reason as to how the present situation is distinguished from that of *Enzo Biochem*. Absent such a distinction, Applicants submit that on this basis alone, the present written description rejection must be withdrawn.

In addition, as noted in Applicants' December 5th and October 11th replies,

antibodies that recognize the amino acid primary structure of CD55 (DAF) were also available in the art at the time the present application was filed (see, e.g., Hara et al., Immunol. Lett. 37:145-152, 1993; copy enclosed with Applicants' August 30, 2004 reply). In fact, Karnauchow et al. (Journal of Virology 70:5143-5152, 1996) cited by the Office in the April 11, 2006 Office Action describes an antibody that binds wild-type CD55 (DAF). These publicly available antibodies allow one skilled in the art to identify and isolate the 82 kD CD55 glycoprotein expressed by the 23132 cell line. There can be no question that, at the time of filing, Applicants were in possession of the glycostructure recited in the present claims. The 35 U.S.C. § 112, first paragraph rejection should be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1, 4, 42, 43, and 45-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vollmers et al. (Cancer 76:550-558, 1995; "Vollmers") as evidenced by Hensel et al. (Cancer Research 59:5299-5306, 1999; "Hensel"). In particular, the Office states (page 4):

> The 23132 cell extract isolated in Vollmers is the same as Hensel's and inherently contains the same glycoprotein of about 82 kDa.

Applicants respectfully traverse this basis for rejection.

As noted above, the *isolated* glycoprotein of claim 1 is required to have an apparent molecular weight of 82 kD in SDS polyacrylamide gel electrophoresis.

Similarly, claim 50 is directed to an *isolated* glycoprotein that contains a section of a glycosylated human CD55 protein expressed by adenocarcinoma cell line 23132, but not by a normal cell. The glycosylated human CD55 protein has an apparent molecular weight of about 82 kD in SDS polyacrylamide gel electrophoresis, and the section of the glycosylated human CD55 protein includes a tumor-specific N-linked glycostructure.

With regard to isolating the about 82 kD glycoprotein, Applicants' specification teaches, under "Results" at page 28 of the English language specification:

> In Western-blot analysis of extracts from total cell lysates of gastric carcinoma cell line 23132 ... antibody SC-1 reacted with a protein with a relative molecular mass of about 50 kD. By altering the stringency (1M of NaCl) and *with the use of membrane preparations*, it was possible to detect other proteins with approximately 70 kD and approximately 82 kD ... These proteins were *isolated from the membrane fractions* and purified by sequential size-exclusion and anion-exchange chromatography. (emphasis added)

As described in the above section of the specification, Applicants did not detect the 82 kD glycoprotein in the total cell lysate. Instead, Applicants needed to alter the stringency and use *membrane preparations* to detect an 82 kD glycoprotein. Moreover, Applicants *isolated* the 82 kD glycoprotein *from the membrane fractions* and then further purified the protein.

The fact that Hensel, after the priority date of the present application, isolates a glycoprotein of about 82 kD from the 23132 cell line used by Vollmers does not establish that Vollmers inherently describes such a glycoprotein. Vollmers used a 23132 cell extract; Hensel, like Applicants, used a membrane preparation. Vollmers describes

neither membrane preparations of 23132 cells nor an isolated glycoprotein having a molecular weight of about 82 kD. The only protein that Vollmers describes has a molecular weight of about 49 kD. A molecular weight of 49 kD is nowhere near 82 kD. Given that Applicants (and Hensel) needed to use membrane preparations of 23132 cells to isolate the 82 kD glycoprotein, Applicants submit that Vollmers, which fails to describe a membrane preparation of 23132 cells, does not expressly or inherently describe an *isolated* protein having the molecular weight required by the claims. Vollmers therefore does not describe each and every element of the claimed invention and Vollmers cannot anticipate claims 1, 4, 42, 43, and 45-56. The 35 U.S.C. § 102 rejection should be withdrawn.

CONCLUSION

Applicants submit that the application is now in condition for allowance, and such action is hereby respectfully requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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